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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,880	FRUEHAUF, JOHN P.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 22-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

The amendment filed on 8/17/06 in response to the previous Non-Final Office Action (1/27/06) is acknowledged and has been entered.

Claims 1-39 are pending. Claims 1-19 and 22-39 have been withdrawn previously for non-elected invention. Claims 20 and 21 are under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

Response to Arguments

Rejection under 35 USC § 102

1. Claims 20-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mechetner et al., as evidenced by Sharom F and Gottesman et al., as stated below:

> Mechetner et al., disclose a method for identifying of a tumor and cells resistant to Taxol, a taxane chemotherapeutic drug, by increased P-glycoprotien (Pgp) expression in human breast cancer cells. P-glycoprotien is ATP transporter protein having ATPase activity as evidenced by Sharom F (line 13-15) and Gottesman et al., (page 49, col 3, para 2, to page 50). Mechetner et al., disclose that Pgp expression in the samples is determined by flow cytometry or immunohistochemistry (p 391, col 1). Mechetner et al., also disclose the comparison and quantization of Pgp expression in the clinical specimen of breast carcinoma from the patients treated and untreated with Taxol (p 393, col 2, last para and table 2). Mechetner et al., disclose that higher levels of Pgp expression in the samples resistant to Taxol and that the degree of Pgp expression strongly correlated with the degree of drug resistance in the clinical specimen studies (fig 3, page 395 and page 394, col 1, para 3). Mechetner et al., further disclose the degree of expression of Pgp in breast cancer will significantly contribute to the levels of clinical resistance to Taxol (p 396, col 1, last para).

The response filed 8/17/06 has been carefully considered but is deemed not to be persuasive. Applicant argues that Mechetner et al., compare gene expression levels only among cancerous cell lines, while the claims of application compare the gene expression levels in cancerous cells to gene expression in non-tumor cells. In response to this argument, the objective method of claims is identifying a tumor or cells that are resistant to taxane chemotherapy by determining the levels of a gene expression comprising increased p-glycoprotein (Pgp or MDR, an ATPase) expression in the taxane resistant tumor cells. To perform the method, one skilled in the art would primarily compare the expression levels of MDR between the non-resistant and resistant samples after taxane treatment. Mechetner et al., have disclosed such method and indicated that the expression of MDR is increased in the taxane resistant cells. In term of the

non-tumor sample, Mechetner et al., did direct to a reference on page 397 (reference 10, Sanfilippo et al.,), which indicates that benign breast lesions or normal breast glands express no or low level of Pgp compared to treated tumors. Mechetner et al., also state that breast carcinoma had not been thought to belong to the group of tumors derived from tissues that intrinsically express Pgp and only 11% of untreated breast cancer cells express Pgp (page 396, col 2). Therefore, one skilled in the art has already clearly known non-tumor or untreated breast tumor tissue expressing low levels of Pgp and as indicated in the Mechetner et al., that expression of Pgp is increased after taxol treatment. Accordingly, the method of Mechetner et al., anticipates the claimed invention. Thus, applicant's argument has not been found persuasive and the rejection is maintained for the reason of record.

2. Claims 20-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Junkun et al., (J Cell Biochem, vol 53, page 135-144, 1993) or Jankun et al., (US Patent 5679350, 1997) as stated below:

> Junkun et al., (JCB) disclose a method for identifying a tumor cells by the levels of expressing Urokinase plasminogen activator receptor (uPAR), alternative name of Urokinase receptor as evidenced by Mesh word search in NCBI (exhibit A), expression on tumor cells. Junkun et al., disclose that the method comprise comparing Urokinase receptor expressed on breast cancer tissue cells to normal breast tissue using immunohistochemical staining (page 137, col 2 to page 138 and figure 2). Junkun et al., further disclose that malignant tumors express higher levels (intensive staining) of uPAR than the normal breast tissues (page 137, col 2)
>
> Jankun et al., (Patent 5679350) disclose a method of identifying tumor cells by the levels of Urokinase plasminogen activator receptor (uPAR) expressed on breast cancer tissues to normal breast tissue by immunohistochemical staining. Jankun et al., disclose that uPAR is highly expressed on the breast tumor compared to normal breast tissues (col 11, line 65- col 13).

The response filed 8/17/06 has been carefully considered but is deemed not to be persuasive. Applicant argues that the claims of the instant application require the identification of cells and/or tumors that are resistant to taxane chemotherapeutic drugs and neither Jankun (JBC) nor Jankun ('350 patent) purports or suggest the identification of tumor and/or cells that are resistant to taxane chemotherapeutic drugs. In response this argument, the claim 20 recites, "*a method for identifying a tumor or cells comprising the tumor that are resistant to taxane chemotherapeutic drugs...determining gene expression of urokinase receptor (uPAR)*". Because of the open language of "comprising" in the claim, the Office interprets that the claimed method comprises identifying a tumor/cell or a tumor/cell resistant to taxane

chemotherapeutic drugs. Both Jankun (JBC) and Jankun ('350 patent) disclose a method of identifying a breast tumor cells that have an increased level of uPAR compared to normal breast tissue cells. It is clear for one skilled in the art that the method anticipates the claimed method. Thus, applicant's argument has not been found persuasive and the rejection is maintained for the reason of record.

3. Claim 20 remains rejected under 35 U.S.C. 102(b) as being anticipated by Gong et al., (Dev Biol, vol 183, page 166-82, 1997).

> The claim 20 is drawn to a method for identifying a tumor or tumor cells comprising determining gene expression of HIP116 gene and identifying the tumor or cells by increased the expression of the gene in the tumor cells.
>
> Gong et al., disclose a method for identifying tumor cells comprising determining the expression of Zbul gene (HIP116, abstract, line 3) in tumor cells. Gong et al., disclose that HIP116 gene expression is dramatically induced in human tumor lines (abstract, line 10, figure 4 on page 170).
>
> The response filed 8/17/06 has been carefully considered but is deemed not to be persuasive.

The response filed 8/17/06 has been carefully considered but is deemed not to be persuasive. Applicant has the same argument as above, that is, the claims of the instant application require the identification of cells and/or tumors that are resistant to taxane chemotherapeutic drugs and Gong et al., disclose methods directed toward the identification of cells having higher expression levels of HIP116 in tumor cell, not in tumor or cells that are resistant to taxane chemotherapeutic drugs. In response to this argument, as discussed above, because of a open language of ...tumor and/or cells comprising....in the claim, the disclosure of a method of identifying a tumor cells by increased expression of HIP116 in tumor cells compared to normal cells by Gong et al., anticipates the claimed invention. Thus, Applicant's argument has not been found persuasive and the rejection is maintained for the reason of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the

end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER